October 18, 2022

CGS Administrators, LLC Part A and B
Meredith Loveless, MD
Attn: Medical Review
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685
Submitted via email to cmd.inquiry@cgsadmin.com

RE: Proposed LCD DL39383 Sacroiliac Joint Injections and Procedures

Dear Ms. Loveless:

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing approximately 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies.

On behalf of our physician members of the Society of Interventional Radiology (SIR), we would like to respectfully comment on the Proposed Local Coverage Determination (LCD) DL39383 for Sacroiliac Joint Injections and Procedures. This proposed policy states, "D. SIJ Denervation (also called Radiofrequency Ablation or RFA) is considered investigational and therefore not reasonable and necessary." SIR respectfully disagrees and believes this will prevent patient access to this opiate alternative procedure.

There is ample clinical literature regarding the role of RFA in managing SIJ dysfunction. Ferrante et al. reported the first bipolar RF technique in 2001 that created a strip lesion along the posterior portion medial to the SI joint with RF needles inserted at <1-cm intervals. It gave rise to 36% of the patients experiencing at least 50% pain relief for six months.1 Following this, conventional monopolar RFA techniques were used to target the lateral branches of the primary dorsal rami in several studies, which reported sustained relief of pain for six months in over 60% of subjects.2-4 In addition to unipolar and bipolar RFA, other techniques have been successfully used to target the lateral branches of the primary dorsal rami, including cooled RF ablation, Simplicity III RF ablation, and quadrapolar RF ablation.5-7

The highest quality evidence regarding the efficacy of SI joint RFA comes from six Level I manuscripts, including five sham-controlled RCTs.8-11 The first two sham-control trials published showed that in pooled, between-group comparisons that those treated with RFA were approximately four times more likely to achieve ≥50% pain reduction at three months compared with sham.8,9 In reviewing the most recent sham-controlled trials conducted in 2016 and 2018, both experiments showed that all participants reported relief of pain...10,11 However, when comparing both trials, Mehta's sham showed statistical significance in relief of pain for the group treated with a strip-lesioning device.11 A twelve-month follow-up of a previously reported sham-controlled RCT showed favorable results for patients initially treated with RFA and those initially treated with sham but were allowed to cross over.12 Five of
the six Level I trials showed statistically significantly better outcomes than either NSM or sham.8-12 Recent meta-analyses have also supported RFA of the SI joints with findings that patients treated with RFA neurotomy had significantly greater improvement in ODI scores, pain scores, and QoL as compared with controls.13 Additionally, in subgroup analyses, patients who received RF neurotomy greatly improved ODI scores compared with those with sham treatment. Patients treated with RF significantly improved pain scores compared with controls who received sham or medical treatment. Given the above findings in many different studies, RCTs, and meta-analyses, the clinical literature supports the use of RFA of the SI joints in managing pain, disability, and dysfunction originating from the SI Joint.

An interventional pain medicine evidence-based chapter by Vanelderen et al. recommended that the treatment of SI joint pain should start with conservative treatment followed by intra-articular SI joint injection and, if the latter fails to produce only short-term effects, then RFA of the lateral branches from L1 to L3 was recommended.14

It should be clarified that both cooled and heated RF use the heat generated by radiofrequency as an ablative mechanism, with the cooling mechanism using water to cool the tip of the needle to propagate the heat farther into the tissue. Still, both techniques generate heat in the surrounding soft tissues up to approximately 85°C. The literature supports both types of RFA, with the initial techniques focusing on traditional RFA1-3,6-9 and more recent techniques expanding the literature information on cooled and large-volume RFA.11,12,14-17 The advent of cool-RF has been characterized by multiple different studies of this application to treat painful SI joints. Kapural et al. showed in a retrospective review of 27 patients who had chronic low back pain (CLBP) and underwent cooled RFA of the lateral, medial branch nerves that these patients had statistically significant improvements in pain and function and a decrease in opioid use that was durable to at least four months.15 A randomized placebo-controlled study of 28 patients by Cohen et al. compared cooled RF to placebo denervation and found statistically significant improvements in pain and function from the patient's baseline status and a much greater global perceived effect in the treated patients 73 to 93 as compared to the placebo patients.14,3 Karman, et al. studied 15 patients suffering from chronic SI joint pain and found that it reduced the median pain score from eight to a three by month six. The ODI decreased from 36 to 14 during the same time frame.17 These authors also reported a 50% reduction of pain in 80% of the patients and concluded that cooled RFA was influential in the short to intermediate term. Patel et al. showed in a randomized placebo-controlled study that lateral branch RFA using cooled RF was statistically better concerning improvements in pain, function, disability, and quality of life compared to sham treatment. The benefits of the treatment lasted up to and beyond nine months.8 A twelve-month follow-up of these patients showed sustained results for those initially treated with lateral branch RFA.12 A 2016 sham-controlled RCT by Van Tilburg et al. failed to show statistically significant superiority of SI joint RFA over sham. Still, this study was widely criticized due to the statement in the discussion of the trial stating that the criteria and method for diagnosing SI joint pain may have resulted in the selection of some patients without SI joint pain.18 After this, there were two RCTs that evaluated long segment or strip RF lesioning using traditional RFA, one being a double-blind sham-controlled RCT that showed a statistically significant reduction in pain at three months19 and the other being an RCT comparing long segment RFA with
celecoxib that showed statistically significant benefit in pain reduction for the RFA as compared with celecoxib in patients treated for six months.  

An additional sizeable multicenter RCT with 15 sites compared cooled RFA to standard medical management with 210 patients was designed to test the superiority of cooled RFA compared to SMM at three months, with the study carried out for one year. To be included, the patients had to have a response of 50% or more decrease in back pain following an SI joint injection, and the SMM patients were allowed to cross over over after three months. The patients had been in pain for an average of 10 years and had never had an RFA before enrolling in the trial. The three-month results included statistically significant and clinically relevant changes in pain, function, quality of life, disability, and patient global impression of change. This trial is the largest RCT trial to date, demonstrating cooled RFA is statistically significantly superior to standard medical management for the clinical treatment of SI joint-mediated pain. Regarding safety, this large RCT showed nothing unexpected in regard to adverse events, no persistent, significant adverse events, and no differences in AEs, regardless of whether the patient was treated unilaterally or bilaterally. At the time of the database lock, 47 patients in the cooled RFA had completed the 12-month visit with a mean pain score of 3.4, down from 6.3 at the beginning of the trial and down from 3.8 at the 3-month time point. In summary, there is ample literature support for cooled RFA, including case reports, case series, two meta-analyses, three systematic reviews, four blinded sham-controlled RCTs, and a large multicenter prospective RCT. In addition to the high-quality data, there are six Level III and Level IV manuscripts and three technological contributions to the literature. In summary, there is strong literature support for both heated and cooled RFA.

In performing RFA of the SI joints, several factors have been found to influence outcomes. These include preprocedural pain intensity, age > 65 years, and pain radiating below the knee, all significant predictors of failure. Notwithstanding these factors, which have been found to influence the outcome, no single clinical variable, including the type of RFA (cool or standard), has been shown to have significantly better treatment results. There are also multiple RCTs, including sham-controlled trials and large trials comparing SI joint RFA to standard medical management, all showing statistically significant between-group comparisons with SI joint RFA over either sham or SMM regardless of whether the RFA is cooled or traditionally heated. Only one Level II study compared thermal and cooled RFA. This report supported all three techniques as effective for treating SI joint pain for up to 12 months and concluded that standard thermal and cooled RFA were similar. Also, no type of RFA is superior to the other.

In summary, multiple RCTs, including sham-controlled trials and large trials comparing SI joint RFA to standard medical management, show statistically significant between-group comparisons with SI joint RFA over either sham or SMM regardless of whether the RFA is cooled or traditionally heated.

The innervation was described by Solonen, who reported the innervation is derived from the lumbosacral trunk, the superior gluteal nerve, and the dorsal rami of S1 and S2. Ideda described the anterior joint as innervated by the ventral rami of L5 and S2 nerves from the sacral plexus. These nerves are not accessed by traditional dorsal nerve treatments. Szadek et al. showed the anterior SI
Ligaments are innervated by the lumbosacral trunk, which is also anterior and not reached by conventional dorsal treatments. There are some reports of the innervation carrying noxious stimuli being from the dorsal portion, but the most recent study showed that although most of the innervation is from the posterior portion of the joint, there is still some ventral nerve contribution by primarily the L4, L5, and S1 nerves but also some from S2. In summary, most but not all nerves transmitting noxious stimuli can be reached by the traditional dorsal treatment methods.

The best quality data measures clinical response from six months to one year and has significantly improved the measured clinical parameters to at least six months. When comparing the RFA of the SI joint directly to non-surgical management and SI joint fusion, this shows a response of SI joint RFA of approximately six months. The QALY for SI joint RFA following physical therapy and steroid injections is 2.52. It is less than fusion (3.27) and similar to initial RF treatment or no RFA (2.47) and treatment with RFA only (2.49). Therefore, the most cost-effective application of RFA of the SI joint was after failed NSM or when the patient started with RFA. The median duration assumption to calculate the cost-effectiveness of RFA is 7.9 months based on the current RFA evidence. In summary and based on the existing literature and what is clinically and financially sustainable, an adequate length of time for an RFA procedure of the SI joint(s) to last is six months.

The Society of Interventional Radiology believes that all of the supporting evidence above qualifies Sacroiliac Joint (SIJ) Denervation, also referred to as SIJ Radiofrequency Ablation (RFA), as a reasonable and medically necessary intervention to treat patients suffering from SIJ dysfunction and chronic pain. The indication that RFA is investigational and, thereby, not medically necessary will prevent patient access to a highly effective opiate alternative treatment option. In addition, the evidence above clearly proves that using RFA successfully treats unmanaged pain within the SIJ population. Most importantly, it minimizes the probability of said group transitioning into opioid abuse. Therefore, the Society strongly recommends that the proposed local coverage determination (LCD) DL39383 for sacroiliac joint injections and procedures properly reflect radiofrequency ablation (denervation) as a medically necessary and reasonable treatment for patients suffering from sacroiliac joint dysfunction and pain.

SIR appreciates the opportunity to provide feedback on this proposed policy. If additional information is required, don’t hesitate to contact SIR’s Manager of Coding and Reimbursement, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Parag J. Patel, MD, FSIR
President, Society of Interventional Radiology
References


## Summary of Evidence for RFA of Sacroiliac Joint

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<thead>
<tr>
<th>Author, Year</th>
<th>Title</th>
<th>Study Design</th>
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<tr>
<td>Mehta (2015)</td>
<td>The Effects of Radiofrequency Neurotomy Using a Strip-Using Device on Patients with Sacroiliac Joint Pain: Results from a Single-Center, Randomized, Sham-Controlled Trial</td>
<td>RCT</td>
<td>Pain Physician</td>
<td>Nov 2015; 16(5): 663-678.</td>
<td>47</td>
<td>Level I</td>
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<tr>
<td>Van Tilburg (2016)</td>
<td>Randomized Sham-controlled Double-blinded Multicenter Clinical Trial to Assess the Effect of Percutaneous Radiofrequency Treatment for Sacroiliac Joint Pain: Three-month Results.</td>
<td>RCT</td>
<td>Clin J Pain</td>
<td>Nov 2016; 32(10): 913-924.</td>
<td>60</td>
<td>Level I</td>
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<tr>
<td>Zhang (2014)</td>
<td>Tomography-guided parasacral sacroiliac joint radiofrequency neurotomy versus placebo for alleviating symptoms: an open-label, randomized, and controlled trial</td>
<td>RCT</td>
<td>Rheumatol Res</td>
<td>Sep 2014; 24(3): 199-206.</td>
<td>155</td>
<td>Level I</td>
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<tr>
<td>Patel (2011)</td>
<td>A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain</td>
<td>RCT</td>
<td>Pain Med</td>
<td>Mar 2011; 12(3): 217-258.</td>
<td>51</td>
<td>Level I</td>
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<td>Nishant Patel (2015)</td>
<td>Twelve-month follow-up of a randomized trial assessing cooled radiofrequency denervation as a treatment for sacroiliac joint pain</td>
<td>Randomized Trial</td>
<td>Pain Practice</td>
<td>Oct 2015; 16(9): 941-950.</td>
<td>57</td>
<td>Level I</td>
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<tr>
<td>Cohen 2006</td>
<td>Randomized placebo-controlled study evaluating lateral branch radiofrequency ablation for sacroiliac joint pain</td>
<td>RCT</td>
<td>Anesthesiology, 2006 Aug 20; 105(2):279-88</td>
<td>28</td>
<td>Level II</td>
<td>A randomized, placebo-controlled study was conducted in 28 patients with injection diagnosed sacroiliac joint pain. Fourteen patients received 2.5-g primary lateral and 5-g lateral branch radiofrequency ablation using custom-made technology followed by local anesthetic block, and 14 patients received the local anesthetic block followed by placebo ablation. Patients who failed to respond to placebo injections were noted and were treated with radiofrequency ablation using conventional technology. One, 3, and 6-months post-procedure, 22 (91%), 19 (79%), and 6 (25%) of radiofrequency treated patients experienced a 50% pain relief and significant functional improvement. In contrast, only 2 (14%) patients in the placebo group experienced significant improvement at their three-month follow-up, and none experienced benefits 6 months post-procedure. In the crossover group (n=13), 7 (54%), 6 (46%) and 4 (31%) patients experienced improvement at 1, 3, and 6-months post-procedure.</td>
</tr>
<tr>
<td>Chia-Lung Shih 2006</td>
<td>A comparison of efficacy among different radiofrequency ablation techniques for the treatment of lumbar facet and sacroiliac joint pain: A systematic review and meta-analysis</td>
<td>Systematic Review</td>
<td>Clinical Neurology and Neurosurgery, 2006 Sep; 105(5):330-339</td>
<td>25 RCT (n=1,139)</td>
<td>Level II</td>
<td>Thermal, pulsed, and cooled radiofrequency ablation techniques in the treatment of LF or SI with follow-up of 3, 6, and 12 months were compared with meta analysis. Results suggest that these RFA techniques were effective for treating LF or SI for up to 12 months. Efficacy of the three techniques did not reach statistical significance but possibly revealed a trend for variance in efficacy. At 12 months, the efficacy of standard thermal and cooled RFA was similar (p=0.85). For LF, the benefit for efficacy of cooled RFA was the most effective, standard thermal radiofrequency was second and pulsed was the least effective only in follow-up at 3 months.</td>
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<tr>
<td>Chappel 2003</td>
<td>Radiofrequency denervation for chronic back pain: a systematic review and meta-analysis</td>
<td>Systematic Review</td>
<td>BMJ Open. 2013 Jul 24; 3(7):e002854</td>
<td>5 studies (n=383)</td>
<td>Level II</td>
<td>Review included RCTs comparing RFA to sham or medical treatment in patients with chronic LBP with follow-up from 3 to 3 months, and a study that had follow-up to 12 months. This meta-analysis did not include pulsed RFA. Low quality evidence indicated that RFA can provide a modest reduction in pain at 6 to 12 months follow-up, but there was no significant reduction in pain in the single RCT (n=131) that had &gt;12 month follow-up.</td>
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<tr>
<td>CH Chen 2019</td>
<td>Radiofrequency neurotomy in chronic lumbar and sacro-iliac joint pain: A meta-analysis</td>
<td>Systematic PRISMA Meta-Analysis</td>
<td>Medicine 2019; 98(9):236</td>
<td>15 Studies (n=1,111)</td>
<td>Level II</td>
<td>This systematic review and PRISMA meta-analysis compared the clinical effectiveness of various RF (percutaneous, cooled and pulsed) procedures to conservative non-surgical approaches for the management of chronic lumbar and SI pain. Patients treated with RF neurotomy (n=111) had significantly greater improvement in ODI scores, pain scores and ODI, as measured by EOD-10 compared to controls (n=91); however significant heterogeneity was observed when data were pooled from eligible studies. In subgroup analysis, patients who received RF had a significantly greater improvement in ODI compared to those with sham treatment. Patients treated with RF also had significantly greater improvement in pain scores compared to controls who received sham or medical treatment. The authors conclude that use of RF neurotomy as an intervention for chronic lumbar and sacroiliac joint pain led to improved function.</td>
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<td>Hui-Hui Sun 2018</td>
<td>The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain</td>
<td>A PRISMA-compliant meta-analysis</td>
<td>Medicine 2019; 97(16):e1695</td>
<td>7 Studies (n=147)</td>
<td>Level II</td>
<td>7 studies with a total of 147 eligible patients demonstrated that pain intensity significantly decreased after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.83 (95% CI 1.89 to 5.77, P = 0.000), and 3.69 (95% CI 1.73 to 5.65, P = 0.000) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) respectively. Disability also improved significantly after treatment compared with that measured before treatment. The MD was 13.18 (95% CI 12.27 to 14.09, P = 0.000) as measured by the Oswestry Disability Index (ODI). Seventy-one percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.011 (95% CI: 0.000-0.003, P=0.000)</td>
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**Systematic Reviews & Meta-Analyses**

- Thermal, pulsed, and cooled radiofrequency ablation techniques in the treatment of LF or SI with follow-up of 3, 6, and 12 months were compared with meta analysis. Results suggest that these RFA techniques were effective for treating LF or SI for up to 12 months. Efficacy of the three techniques did not reach statistical significance but possibly revealed a trend for variance in efficacy. At 12 months, the efficacy of standard thermal and cooled RFA was similar (p=0.85). For LF, the benefit for efficacy of cooled RFA was the most effective, standard thermal radiofrequency was second and pulsed was the least effective only in follow-up at 3 months.

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<tr>
<td>A. Ach (2017)</td>
<td>Effects of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The Most Randomized Clinical Trials.</td>
<td>Non-Biased RCT</td>
<td>Anesthesiology</td>
<td>218</td>
<td>Level III</td>
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<tr>
<td>K. T. Leitao A (2020)</td>
<td>Conventional (Simbly I) and Cooled (Sinergy) Radiofrequency for Sacroiliac Joint Denervation: One-Year retrospective study comparing two devices</td>
<td>Retrospective observational</td>
<td>Pain Medicine</td>
<td>43</td>
<td>Level III</td>
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<tr>
<td>M. N. R. Chung, MD, PhD (2013)</td>
<td>Comparative outcomes of cooled versus traditional radiofrequency ablation of the bilateral branches for sacroiliac joint pain</td>
<td>Retrospective Review</td>
<td>Clinical Pain</td>
<td>35</td>
<td>Level III</td>
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**Technology Papers**

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<tr>
<td>C. Codere (2023)</td>
<td>Comparison of fusion volumes and shapes produced by a radiofrequency system with a cooled, a non-cold, and a non-radiofrequency probe</td>
<td>Technical</td>
<td>-</td>
<td>-</td>
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<tr>
<td>J. Bell (2024)</td>
<td>The science of conventional and water-cooled monopolar radiofrequency ablation: an electrical engineering point of view</td>
<td>Technical</td>
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**Outcomes**

- Nonblinded multicenter RCT of radiofrequency denervation in 218 of 254 patients with 95% confidence interval (95% CI) of 0.63 to 0.84, with a p-value of 0.001. The treatment was significantly more effective than placebo, with a 25% reduction in pain intensity at 4 weeks and a 50% reduction at 6 months.
- A total of 11 diagnostic accuracy studies and 14 therapeutic studies were included. Evidence for diagnostic accuracy is Level I for dual diagnostic blocks with at least 92% pain relief below the criterion standard and Level II for evidence in single diagnostic blocks with at least 93% pain relief above the criterion standard. The evidence for cooled radiofrequency neurectomy in managing sacroiliac joint pain is Level II to III. The evidence for conventional radiofrequency neurectomy, extracorporeal shock waves, and percutaneous injections with steroids is Level II to III.

- Average Sinvaly group NRS and CGI scores were consistently less than those in the Sinoploski cohort at each post-RF denervation follow-up, and such differences were statistically significant at 1 and 2 months. The Sinoploski trial procedure was completed approximately 1.5 times faster.
- Both cooled and traditional RF provided 4-gain pain reduction 6 months in majority of the patients.
- The results of CRFA for LEN was reported 4-6 months post-treatment. A significant decrease in mean VAS pain scores from baseline was observed in all groups at follow up. The mean VAS pain scores at 4 months group 18.2 ± 8.0 vs 28.2 ± 9.4, group 2 18.2 ± 8.0 vs 29.2 ± 9.4, group 3 18.2 ± 8.0 vs 29.2 ± 9.4, group 4 18.2 ± 8.0 vs 30.2 ± 9.4 and group 5 18.2 ± 8.0 vs 31.2 ± 9.4.
- The results of cooled RF LEN in on quality of life subjective quality of life was much improved. At 12 months post CRFA, 90% of baseline auditory was stoppedrip and 90% reported using less.
- Cooled RF was a demonstrated that VAS decrease of 3.9 points on a 10-point scale from 6 to 4 was seen after 6 months and of 9.4 after 12 months. Lower median pain was reported with decreased scores in response to anti-inflammatories drugs NSAIDS by 50%. Decreased pain lasted for 12 months.
- Significantly better outcomes were reported by patients with BMI ≥ 30 kg/m² in ≥ 10 patients cooled RF showed a significant reduction in percentage of lost at both points on the NRS. Mean Numeric Pain Scale decreased from 2.11 ± 1.20 to 1.13 ± 1.24. Mean Patient Global Evaluation of Pain was improved (11.42 ± 2.52 and Global Pain Relief Effect was reported to be positive in all patients at two years post CRFA.

**Outcomes**

- Seventy-seven patients with refractory injections-refractory SI joint pain underwent SI joint denervation at a academic institutions. A composite binary variable “success” outcome was pre-defined as greater than 50% reduction in pain lasting at least 6 months coupled with a positive global perceived effect. Secondary outcome measures included Oswestry Disability Index. Forty patients (94%) obtained a positive outcome. The use of cooled, rather than conventional RF, was associated with a higher percentage of positive outcomes.